K113088

MAY - 2 2012

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

Submitted by:
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Contact person:
Don Bobo (dbobo@innerspacemedical.com)

Predicate 510K Device:
K013705

510(k) Number Not assigned

Device Name
Hummingbird Subdural H900DS (Drainage and ICP)
Hummingbird Subdural - H800S (ICP only)

Trade names
Hummingbird Subdural H900DS (Drainage and ICP)
Hummingbird Subdural - H800S (ICP only)

Common Name
Subdural Catheter

Classification:
Short-term catheter

Class II (Per 21 CFR Part 882.1620 Intracranial pressure monitoring device.)

Product Code GWM, HCA

Predicate Devices

K013705 InnerSpace, Inc (Tunneled catheter)

Submittal type 510-(k)

This submission adds an indication for use of the InnerSpace tunneled ventricular catheter used to measure ICP and drain CSF. The added indication is its use to measure intracranial pressure (ICP) and/or drain CSF in the subdural space. A second catheter without a drainage lumen used to measure ICP is also included.

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Device Description

The HS900DS device is a dual lumen catheter, the outer lumen is for drainage of CSF, the inner lumen is a gas filled path connected to a bladder/balloon. The bladder is inserted into the space where pressure is to be measured. The distal end of the gas filled lumen is connected to a pressure transducer, which provides a measurement of the pressure in the lumen. The H800S is similar to the H900DS except it only contains the pressure sensing lumen.

Product Function

The Subdural catheter provides the ability to measure ICP in the subdural space and, in one model, provides the ability to also drain fluid that collects on the brain.

Pressure Sensing

ICP is sensed by Air Coupled Transduction, which is identical to that in the predicate device. In this system, the pressure in a partially filled sleeve bladder on the body of the catheter responds to Bolyle's law in accordance to $P_1V_1=P_2V_2$. The pressure developed within the catheter is conveyed via a dedicated airline to an external pressure.

Validation

The models are substantially equivalent to the predicate tunneled catheters because they use the same physical characteristics, use the same pressure sensor which meets the requirements of AAMI NS28 1988 Intracranial Pressure Monitoring Devices and they allow external zeroing of pressure. They use the same materials, all of which have been shown to be biocompatible and to function well in the intended application.

Indications For Use

The use of the Hummingbird H900DS Subdural Catheter is indicated for direct measurement of intracranial pressure and drainage of CSF in the subdural space.

The use of the Hummingbird H800S Subdural Catheter is indicated for direct measurement of intracranial pressure in the subdural space

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Innerspace, Inc.
% Mr. Don Bobo
1622 Edinger Ave. Ste. C.
Tustin, CA 92780

MAY - 2 2012

Re: K113088
Trade/Device Name: Hummingbird Subdural H900DS & H800S
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial pressure monitoring device
Regulatory Class: Class II
Product Code: GWM, HCA
Dated: April 3, 2012
Received: April 20, 2012

Dear Mr. Bobo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lysia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113088

Device Name: Hummingbird Subdural H900DS & H800S

Indications for Use:

The use of the Hummingbird H900DS Subdural Catheter is indicated for direct measurement of intracranial pressure and/or drainage of CSF in the subdural space.

The use of the Hummingbird H800S Subdural Catheter is indicated for direct measurement of intracranial pressure in the subdural space.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

JOE HUTTER

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K113088